

JUL 31 2003

K032188

510(k) Notification  
Nichols Advantage Aldosterone  
Date: 07/11/03 (revised)

## 12.0 Concluding 510(k) Summary

*This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.*

### 1. Name of Manufacturer, Contact Person and Date Summary Prepared:

Nichols Institute Diagnostics

1311 Calle Batido

San Clemente, CA 92673

Phone: 949-940-7260

FAX: 949-940-7313

Contact Person: Jimmy Wong, Manager of Clinical and Technical Affairs

Date Prepared: July 11, 2003

FOOD AND DRUG BRANCH

### 2. Device Name:

Trade/Proprietary Name:

Nichols Advantage® Aldosterone

Common Name:

Aldosterone immunoassay

Classification Name:

Radioimmunoassay, Aldosterone

### 3. Classification: Class II

Regulation Number: 862.1045

Product Code: CJM, Clinical Chemistry

### 4. Predicate Device: Diagnostic Product Corporation Coat-A-Count Aldosterone

### 5. Device Description:

The Nichols Advantage® Aldosterone assay contains sufficient reagents for 100 tests. The assay is a competitive binding assay for aldosterone in human serum or plasma.

### 6. Intended Use:

The Nichols Advantage® Aldosterone assay is intended for use with the Nichols Advantage® Specialty System to quantitatively measure aldosterone in human serum and EDTA plasma. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

### 7. Comparison to Predicate Device:

The Nichols Advantage® Aldosterone (Y) was compared to the DPC Coat-A-Count Aldosterone RIA (X) previously cleared by the FDA (K831178, 5/27/83). One hundred three (103) remnant serum samples in which the clinical diagnosis were unknown were assayed in duplicate by both methods following each manufacturers' directions. The range observed with method "X" was 2.7 to 125 ng/dL; range for method "Y" was 2.7 to 120 ng/dL. Passing Bablok regression analysis of these data yielded an equation of  $Y = 1.04X + 0.1$  (95% confidence intervals for slope and intercept were 0.98 to 1.10, and -1.0 to +1.1 respectively). Deming regression analysis of these data yielded an equation of  $Y = 1.09X - 0.6$  (95% confidence intervals for slope and intercept were 1.03 to 1.15, and -3.2 to +2.1 respectively). Pearson's correlation coefficient (r) of the paired data was 0.96.

### 8. Similarities:

- Specimen type is identical for both methods.
- Both assays use human aldosterone standards, and both report values using the same units: ng/dL.
- Both assays use a specific antibody to aldosterone, use competitive protein binding with labeled aldosterone to measure the hormone directly in serum or plasma samples.

#### 9. Differences:

The following differences pertain to differences in immunoassay technology and do not affect the intended uses of each assay.

Feature	Nichols Aldosterone	DPC Aldosterone
Sample Size:	250 µL serum or EDTA plasma	200 µL serum or plasma
Binding Technology	Magnetic particles - avidin coated	Antibody coated tubes
Incubation steps and temperature:	3 steps, 10 minutes each @ 37°C	18 hours @ 15-28°C
Analytical sensitivity	1.2 ng/dL	1.1 ng/dL
Sample Bias	EDTA values are lower	EDTA values are higher

#### 10. Comparison of Performance Characteristics

Feature	Nichols Aldosterone	DPC Aldosterone
Within-Run Precision (%CV)	2.9-14.0%	2.3-5.4%
Total Precision (%CV)	4.9-18.6%	3.8-15.7%
Recovery	88-110%	86-111%
Linearity	91-116%	100-119%

**Conclusions:** These data, which were provided to FDA, demonstrate safety and effectiveness of the Nichols Advantage® Aldosterone for its intended in vitro diagnostic use. Furthermore, based on performance characteristics, the Nichols Advantage® Aldosterone assay is substantially equivalent to the predicate method.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**JUL 31 2003**

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Nichols Institute Diagnostics  
c/o Alfredo J. Quattrone, Ph.D., DABT  
California Department of Health  
Food & Drug Branch  
P.O. Box 942732 (MS-357)  
Sacramento, CA 94234

Re: k032188  
Trade/Device Name: Nichols Advantage Aldosterone  
Regulation Number: 21 CFR 862.1045  
Regulation Name: Aldosterone test system  
Regulatory Class: Class II  
Product Code: CJM; JIS; JJX  
Dated: July 15, 2003  
Received: July 17, 2003

Dear Dr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

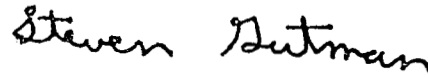
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

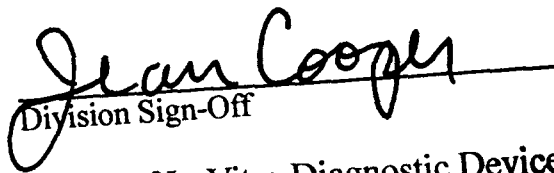
#### 4.0 Indications For Use Statement

##### INDICATIONS FOR USE STATEMENT

510(k) Number: K032188

Device Name: Nichols Advantage Aldosterone

**Indications for Use Statement:** The Nichols Advantage® Aldosterone assay is intended for use with the Nichols Advantage® Specialty System to quantitatively measure aldosterone in human serum and EDTA plasma. Aldosterone measurements are used in the diagnosis and treatment of primary aldosteronism (a disorder caused by excessive secretion of aldosterone by the adrenal gland), hypertension caused by primary aldosteronism, selective hypoaldosteronism, edematous states, and other conditions of electrolyte imbalance.

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K032188

(Please Do Not Write Below This Line – Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

☒ Prescription Use  
(Per 21 CFR 801.109)

Or

☐ Over-The-Counter Use  
(Optional Format 1-2-96)